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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,481	06/23/2003	Andrew Fensome	AHPWA25AUSA	8944

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,481	FENSOME ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/8/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-16 AND 25-28 ARE PRESENTED FOR EXAMINATION

Applicants' Response filed March 5, 2004 and Information Disclosure Statement filed September 22, 2003 have been received and entered into the application. Accordingly, claims 17-24 have been canceled. Also, as reflected by the attached, completed copy of form PTO/SB/8a, the cited references have been considered.

As per the restriction requirement set forth in the previous Office action, applicants have elected, without traverse, the invention of Group I, claims 1-16 and 25-27. Claim 28 will be examined along therewith. Insofar as the claims directed to the non-elected inventions have been canceled, the requirement for restriction is hereby withdrawn.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 28, under the definition of R^5, a definition for "(ii)" is not set forth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/66570 ("WO'570, cited by applicants) and applicants' acknowledgment at page 4, lines 3-5 of the present specification in view of Gast et al. (U.S. Patent Application Publication No. 2002/0061875, cited by the Examiner).

Applicants' acknowledge and WO'570 teaches the presently claimed cyclothiocarbamate derivates (present specification at page 4, lines 3-5 and WO'570 at the abstract and page 7, line 1 – page 19). WO'570 further teaches that the compounds are progesterone agonists and useful in methods for inducing contraception and that progesterone agonists are used in birth control formulations, typically in the presence of an estrogen agonist (estrogen agonist meeting the requirement in both claims 1 and 28 for "a selective estrogen receptor modulator") (page 1, lines 6-8). Salts and prodrugs of the cyclothiocarbamate compounds are taught at the section bridging pages 31-32 of WO'570. At page 33 of WO'570 dosages of from about 0.5 to 500 mg are taught.

The differences between the above and the claimed subject matter lie in that the above does not teach:

(1) the claimed cyclothiocarbamate compounds and the selective estrogen agonist in a single or separate compositions;

(2) the selective estrogen agonists of present claim 4; and

(3) the claimed treatment regimen (present claim 6) and dosage amounts of the estrogen receptor modulators.

However, to the skilled artisan, the claimed subject matter would have been obvious because:

(1) Gast et al. teach that the majority of oral contraceptives consist of a combination of a progestin and an estrogen that are administered concurrently for 21 days (page 1 section [0003]. Also, Gast et al. teach progestin/antiestrogen containing contraceptive compositions and methods of providing contraception to a female child bearing age therewith wherein the composition is administered daily during the 28-day (i.e., "about" 21 days per present claim 6) menstrual cycle (page 1, section [0006]). As the antiestrogens, Gast teaches antiestrogen compounds at page 1, section [0006] – page 6, section [0026] and such compounds as raloxifene (1-600 mg), droloxifene (1-600 mg), idoxifine (1-600 mg), nafoxidine (0.5-600 mg), toremifene (0.1-600 mg), levomelixifene (0.5-600 mg) EM-800) (page 6, section [0029]). At section [0034], lines 4-6, it is set forth that it is preferred, i.e., not required, that the progestin and antiestrogen be combined in the same dosage unit. Contraceptives kits are taught at page 7, section [0035].

The skilled artisan would have been motivated to employ the cyclothiocarbamate derivates of WO'570 for the progestins of Gast et al. because each function as progesterone agonists and the skilled artisan would have had at least a reasonable expectation that such compounds could be interchanged and that similar results would result.

Double Patenting

Claims 1-16 and 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91 and 92 and each of the claims directly and indirectly upon which they depend of U.S. Patent No. 6,436,929 (cited by applicants) or claims 57, 83 and 97 and the claims on which they directly or indirectly depend of U.S. Patent No. 6,509,334 (cited by the Examiner) in view of WO'570 and Gast et al. (U.S. Patent Application Publication No. 2002/0061875, cited by the Examiner).

The differences between the above and the claimed subject matter lie in that the above does not teach:

(1) the claimed cyclothiocarbamate compounds in combination with selective estrogen agonist in a single or separate compositions;

(2) the selective estrogen agonists of present claim 4; and

(3) the claimed treatment regimen (present claim 6) and dosage amounts of the estrogen receptor modulators.

However, to the skilled artisan, the claimed subject matter would have been obvious because:

(1) WO'570 teaches the presently claimed cyclothiocarbamate derivatives (WO'570 at the abstract and page 7, line 1 – page 19). WO'570 further teaches that the compounds are progesterone agonists and useful in methods for inducing contraception (page 1, lines 6-8) and that progesterone agonists are used in birth control formulations, typically in the presence of and estrogen agonist (estrogen agonist meeting the requirement in both claims 1 and 28 for "a selective estrogen receptor modulator"). Salts and prodrugs of the cyclothiocarbamate

compounds are taught at the section bridging pages 31-32 of WO'570. At page 33 of WO'570 dosages of from about 0.5 to 500 mg are taught.

(2) Gast et al. teach that the majority of oral contraceptives consist of a combination of a progestin and an estrogen that are administered concurrently for 21 days (page 1 section [0003]. Also, Gast et al. teach progestin/antiestrogen containing contraceptive compositions and methods of providing contraception to a female child bearing age therewith wherein the composition is administered daily during the 28-day (i.e., "about" 21 days per present claim 6) menstrual cycle (page 1, section [0006]). As the antiestrogens, Gast teaches antiestrogen compounds at page 1, section [0006] – page 6, section [0026] and such compounds as raloxifene (1-600 mg), droloxifene (1-600 mg), idoxifine (1-600 mg), nafoxidine (0.5-600 mg), toremifene (0.1-600 mg), levomelixifene (0.5-600 mg) EM-800) (page 6, section [0029]). At section [0034], lines 4-6, it is set forth that it is preferred, i.e., not required, that the progestin and antiestrogen be combined in the same dosage unit. Contraceptives kits are taught at page 7, section [0035].

The skilled artisan would have been motivated to employ the cyclothiocarbamate derivates of WO'570 for the progestins of Gast et al. because each function as progesterone agonists and the skilled artisan would have had at least a reasonable expectation that such compounds could be interchanged and that similar results would result.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The Hodgen reference (U.S. Patent No. 6,258,802) cited by the Examiner on the attached Form PTO-892 and not relied upon is included to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 4, 2004